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STATE OF DELAWARE
BOARD OF PHARMACY

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PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, August 16, 2017 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	October 18, 2017

MEMBERS PRESENT

Susan Esposito, R.Ph., Professional Member, President
Hooshang Shanehsaz, R.Ph., Professional Member, Vice President
Bonnie Wallner, R.Ph., Professional Member
Kimberly Robbins, R.Ph., Professional Member
Jay Galloway, Public Member
Gayle MacAfee, Public Member

MEMBERS ABSENT

Tejal Patel, PharmD, Professional Member
Michelle McCreary, Pharmacist Compliance Officer

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III

ALSO PRESENT

Jeremy D. Hess
Jen Raubley
Lisa LeGette
Amit Darwani
Meera Patel
Brenda Poland
Ryan Hines
Jamie Mack
Donna Kemp
Tim DeRose
Debbie Hamilton
Carla Jarosz
Greg Morris

CALL TO ORDER

Ms. Esposito called the meeting to order at 9:30 a.m.

REVIEW OF MINUTES

A motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to table the meeting minutes for June 21, 2017. The motion carried.

A motion was made by Mr. Shanehsaz and seconded by Ms. MacAfee to move forward to agenda item H.1. Naloxone Dispensing - Jamie Mack, Department of Health and Social Services. The motion carried.

Mr. Mack provided the Board with printed materials for review. He stated that legislation has been drafted to provide pharmacists the same protections as practitioners dispensing naloxone. Guidance for practitioners and for patients can be located at www.helpisherede.gov.

The Board also suggested that the Naloxone Bill be included in a newsletter.

UNFINISHED BUSINESS

Statutory and Regulatory Discussion

Telemedicine Pharmacy Regulations Changes, a motion was made by Mr. Shanehsaz and seconded by Ms. MacAfee to table until the September 20, 2017 legislative committee meeting. The motion carried.

Review of Proposed Regulation 1.8, 8.0, 19.0– Changes – Ms. Kelly prepared draft regulations for 1.8, and 8.0. Ms. Esposito read the current regulation 19.0, the Board determined that proper training is the responsibility of the Pharmacist in Charge and the training materials must be available for inspection per regulation.

Review of Tabled Applications - Owens & Minor Distribution, Inc. (IL) - a motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to approve the application. The motion carried.

PRESIDENT'S REPORT

Ms. Esposito provided the following report:

MPJE: As discussed at the June 21st meeting NABP requested representatives from each State to review the questions for the upcoming exam. The committee has received material from NABP and State Regulations from various disciplines to assist with this review which will end Aug 31st.

PMP Survey: Mr. Mangler forwarded a survey on PMP use which asked the user to evaluate various aspects of the process to assist with improving the PMP process.

Naloxone Legislation: The new regulations help with the dispensing of Naloxone in Delaware. A number of Pharmacists were at the signing event; Hooshang Shanehsaz represented the Board of Pharmacy.

NABP Standard Inspection Form: After the last meeting, I asked Michelle McCreary to compare the NABP form with the form currently used in Delaware to see if we can go to that format which would make reporting to other States more consistent.

Physician Assistance Liaison: Tejal Patel has been the Board Representative for the past few years. She has found that her schedule at work will not permit her to attend. I have asked Gayle McAfee if she would consider being our Liaison since the meeting is on the same day as the Medical group. She has kindly consented to do both.

Pharmacy Closing requirement when Pharmacist is not in the main Pharmacy - I was contacted by Walmart Corp. as a survey to State Boards to help them set up policies. I asked that this item be added to the agenda for Board review of present Regulations. I conferred with Eileen Kelly before adding it to the agenda.

Pharmacy Compounding Regulations: The Board received a request concerning the inclusion of USP 800 in our regulations. I conferred with Eileen Kelly and it has been added to our agenda for further discussion. As we found at the NABP Convention many states have surveyed Hospitals and facilities in their state to determine how close to meeting the new standards they are, what costs have been anticipated and what roadblocks are anticipated.

NEW BUSINESS

Ms. Esposito read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

A1-0005081 Colleen J. Whyte
A1-0005082 Taryn L. Hinnars
A1-0005083 Ross Michael Broton
A1-0005084 Justin G. Simpkins
A1-0005085 Camyn H Perry
A1-0005086 Rachel M. Lynch
A1-0005087 Tijo Jose Aikara
A1-0005088 Oyenike O Adegoke
A1-0005089 Eric L. Souder
A1-0005090 Priya Panchal
A1-0005091 Kristen Michele Audley
A1-0005092 Christopher J. Cook
A1-0005093 Richard Taylor Mearhoff
A1-0005094 Michael Adolph Beyer
A1-0005095 Ashley Ward Robold
A1-0005096 Kara Elizabeth Anderson

A motion was made by Ms. Robbins and seconded by Mr. Shanehsaz to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern:

A7-0002462 Melissa Anh Dang
A7-0002463 Elizabeth M. Gleeson
A7-0002464 Jeel Dilipkumar Shah
A7-0002465 Gregory C. Hayes
A7-0002466 Shahrzad Barzin
A7-0002467 Amanda C. Sember
A7-0002468 Katherine Michelle Gibison
A7-0002469 Nguyet Anh Le

A motion was made by Ms. Robbins and seconded by Ms. Wallner to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0002016 Tops Pharmacy, Inc.
A9-0002017 Animart Livestock Pharmacy
A9-0002018 Cedra Pharmacy Inc
A9-0002019 Florida Arthritis & Rheumatology Associates, LLC dba WhiteGloveRx
A9-0002020 Rosemont Specialty Pharmacy dba Pharma Buddies Corp
A9-0002021 Clinical Specialty Infusions of Dallas, LLC
A9-0002022 Valeda Rx, LLC
A9-0002023 Brooksville Pharmaceuticals Inc.
A9-0002024 Healthy Corner Pharmacy Inc.
A9-0002025 OncoMed Pharmaceutical Services of MA, LLC dba Onco360
A9-0002026 WiRx Pharmacy II
A9-0002027 Paragon Infusion
A9-0002028 Avella Patient Access Program, Inc.
A9-0002029 Acutus Rx, LLC
A9-0002030 Rite Aid of Maryland, Inc. dba Rite Aid #4254
A9-0002031 Medi Service of Charlotte, Inc. dba Giant Genie Pharmacy Monroe
A9-0002032 AccuServ Pharmacy
A9-0002033 SPRX, Inc.
A9-0002034 U.S. PharmaMed, LLC
A9-0002035 One Source Pharmacy and Medical Supplies, LLC
A9-0002036 The Art of Medicine
A9-0002037 AIDS Healthcare Foundation dba AHF Pharmacy

A9-0002038 Medworld Pharmacy Inc.
A9-0002039 PDC Pharmacy
A9-0002040 Northside Pharmacy
A9-0002041 Restore Rx, Inc.
A9-0002042 City Drugs NY Corp.
A9-0002043 Blondell Rx Corp
A9-0002044 CareSite Pharmacy
A9-0002045 Frontline Pharmacy Services, LLC
A9-0002046 New York Pharmacy Network, LLC
A9-0002047 Family Pharmacy
A9-0002048 CareZone Pharmacy LLC
A9-0002049 Fairmount Pharmacy Services, LLC
A9-0002050 Caprock Compounding Pharmacy, Inc.
A9-0002051 Wells Specialty Pharmacy, Inc.
A9-0002052 Executive Business Solutions, LLC
A9-0002053 Medcart Specialty Care, LLC dba Medcart Specialty Pharmacy
A9-0002054 Hospital of The University of Pennsylvania - Radnor Pharmacy
A9-0002055 Hospital of The University of Pennsylvania - Perelman Pharmacy

A motion was made by Ms. Robbins and seconded by Mr. Shanehsaz to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0001925 Bound Tree Medical, LLC
A4-0002419 The Procter & Gamble Distributing LLC
A4-0002420 Patterson Medical Supply, Inc
A4-0002421 The Hibbert Group
A4-0002422 ICU Medical Sales, Inc.
A4-0002423 Marnel Pharmaceuticals LLC
A4-0002424 Upsher-Smith Laboratories, LLC
A4-0002425 RxC Acquisition Company
A4-0002426 Golden State Medical Supply, Inc.
A4-0002427 Golden State Medical Supply, Inc.
A4-0002429 FedEx Supply Chain, Inc.
A4-0002430 Athenex Pharma Solutions, LLC
A4-0002431 ICU Medical Sales, Inc.
A4-0002432 Granules Pharmaceuticals, Inc.

A motion was made by Ms. Robbins and seconded by Ms. Wallner to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

A2-0000148 AHP of Delmarva, LLP dba American HomePatient

A motion was made by Ms. Robbins and seconded by Ms. Wallner to approve the ratification of the Medical Gas Distributor applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A3-0001012	Careplus Pharmacy
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A motion was made by Ms. Robbins and seconded by Mr. Shanehsaz to approve the ratification of the Retail Pharmacy application. The motion unanimously carried.

Non-Retail Pharmacy Licensure Approval Ratification

None

Outsourcing Facility

AA-0000043 Wells Pharmacy Network, LLC

AD-0000042 Central Admixture Pharmacy Services Inc

A motion was made by Ms. Robbins and seconded by Ms. Wallner to approve the ratification of the Outsourcing Facility application. The motion unanimously carried.

Pharmacist-In-Charge Interviews

A motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to amend the agenda to add the following for PIC interview: PIC Ryan Hines, Walgreens, Delmar De.

The motion unanimously carried.

Ms. Robbins conducted the Pharmacists in Charge interviews for the following:

PIC - Donna Kemp, Weis Pharmacy Lewes, DE

Board Review of Facility Applications

DermaRite Industries, LLC. (NJ) - a motion was made by Ms. Wallner and seconded by Mr. Shanehsaz to approve the application. The motion unanimously carried.

Athenex Pharma Solutions LLC. (NY) - a motion was made by Mr. Shanehsaz and seconded by Ms. Wallner to table the application. The motion unanimously carried.

RXQ Compounding, LLC (OH) - a motion was made by Mr. Shanehsaz and seconded by Ms. Robbins to table the application. The motion unanimously carried.

Talca Pharmaceuticals Inc. (CA) - a motion was made by Mr. Galloway and seconded by Mr. Shanehsaz to approve the application. Ms. Robbins voted against the approval. The motion carried.

Baxter Healthcare Corp. (MA) - a motion was made by Ms. Wallner and seconded by Mr. Galloway to approve the application. Mr. Shanehsaz abstained. The motion carried.

Ardon Health LLC. (OR) - a motion was made by Mr. Galloway and seconded by Mr. Shanehsaz to approve the application. The motion unanimously carried.

Board Review of Pharmacist Applications

William Mattioli, R.Ph. - Reciprocity (NJ) - a motion was made by Mr. Galloway and seconded by Mr. Shanehsaz to approve the application. The motion unanimously carried..

Continuing Education Review

None

Pharmacist and Pharmacy - Discussion/Action Items

Naloxone Dispensing - Jamie Mack, Department of Health and Social Services – see text above after review of meeting minutes. This item moved to earlier in the meeting.

Review of 24 Del. C. Sec. 2533 (a) and Regulation 3.6 "Closing of Pharmacy When Pharmacist not Present" – Ms. Kelly read the statute and regulation. The Board discussed changing Prescription Department to Prescription Premises in Section 2533. This would allow the Pharmacist to be within the premises allowing necessary breaks to be taken without putting the public in jeopardy. Ms. Kelly will create draft language for this issue in statutory and regulatory updates she is currently working on.

Syringe Status, Hooshang Shanehsaz - Mr. Shanehsaz is asking the Board it's opinion on changing the status of syringes from prescription required to over the counter due to public health access and concerns for spreading of disease like Hepatitis C spread by using dirty syringes. Surrounding states' laws do not prohibit the sale of syringes over the counter. Federal law does not prohibit the sale of syringes over the counter. Mr. Shanehsaz asked if this item could be added to the Controlled Substance Advisory Committee agenda for discussion. He would attend the Controlled Substance Advisory Committee meeting on behalf of the Board of pharmacy to make the request.

Review of Compounding Regulations, Hooshang Shanehsaz – Mr. Shanehsaz stated that he has received questions regarding enforcement of USP800. He suggested that regulation language be changed to state the USP795 and USP797 must be adhered to as well as any future updates to the compounding requirements by the USP. Ms. Kelly stated that regulation 10.0 could be updated to reflect the request above and remove all the current language to simplify this regulation. Ms. Esposito stated that there should be dates of required compliance with this regulation. Ms. Kelly stated that the language could be included to state: “USP deadlines should be adhered to within 1 year of publication of the USP regulation update”. Ms. Shanehsaz suggested that non-compliance by those deadlines should be presented to the Board for review with plans for completion including the proposed deadline for Board approval. Ms. Kelly will prepare draft regulations to reflect these changes for Board review. Mr. Shanehsaz stated that training for the Pharmacist Compliance Officer in the USP800 standards is also required. This training has not been previously made available to the Pharmacist Compliance Officer and is required.

A motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to move forward to agenda item K.1., Review of Hearing Officer Recommendation @11:30 a.m. - Kodwo Bedu Sekyi, R.Ph. The motion carried.

Review of Hearing Officer Recommendation – Kodwo B. Sekyi

Ms. Kelly explained that the Board would be reviewing the Hearing Officer Recommendation in the case of Kodwo B. Sekyi. The parties presented oral exceptions. Carla Jarosz, Deputy Attorney General, spoke for the State. Mr. Sekyi made a statement to the Board as did his attorney, Greg Morris, Esq.. After the parties presented their exceptions, the Board entered deliberations. After deliberations, a motion to accept the Hearing Officer’s conclusions of law was made by Mr. Shanehsaz seconded by Ms. MacAfee. The motion unanimously carried. Mr. Shanehsaz made a motion to amend the Hearing Officer’s recommended discipline to increase the period of license suspension from one year to two years; to increase the period of license probation from two years to five years, subject to both the conditions recommended by the Hearing Officer and further conditions designated by the Board. The motion was seconded by Ms. Wallner. The motion unanimously carried.

COMMITTEE REPORTS

Legislative – Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz, Bonnie Wallner and Gayle MacAfee

Mr. Shanehsaz stated the committee meets immediately following this meeting. Committee is currently discussing tele-pharmacy, language discussed for prescription requirements changes, looking at other states are urgent care regulations.

Continuing Education – Bonnie Wallner, Tejal Patel:

No Report

Consumer Affairs – Jay Galloway, Gayle MacAfee

No Report

Professional Liaisons – Kim Robbins, Tejal Patel and Hooshang Shanehsaz:

Ms. MacAfee stated she attended the Board of Medical Licensure & Discipline (BOMLD) held in July 2017, had no quorum. The next meeting will be held in September 2017. She will attend that meeting.

Controlled Substance Liaisons –Tejal Patel, Hooshang Shanehsaz:

No Report

INSPECTION and PMP REPORT - Michelle McCreary

No Report

Review of Hearing Officer Recommendation @11:30 a.m. - Kodwo Bedu Sekyi, R.Ph.

See above moved prior to I. Committee Reports

Election of Officers

President – Mr. Shanehsaz nominated himself for the position of President of the Board of Pharmacy. There being no other nominations a motion was made by Ms. Robbins seconded by Ms. MacAfee for Mr. Shanehsaz to represent the Board as President.

Vice President - Ms. Wallner nominated Tejal Patel for the position of Vice President of the Board of Pharmacy. There being no other nominations, a motion was made by Ms. Robbins and seconded by Ms. MacAfee for Ms. Patel to represent the Board as Vice President.

BOARD CORRESPONDENCE

None

OTHER BUSINESS BEFORE THE BOARD

Ms. Kelly stated that she and Ms. McCreary would be attending the annual Food & Drug Administration (FDA) meeting held in Maryland.

PUBLIC COMMENT

Mr. Shanehsaz stated he was contacted by a pharmacy in Sussex County stating that Medicaid is requiring HIV medications to be purchased through a Specialty Pharmacy assigned by Medicaid. HIV medication doses cannot be missed without adverse reaction. Mr. Shanehsaz stated that a letter from the Board to the Insurance Commissioner would be appropriate due to the concern of access to care and this requirement could be limiting access to medication to one pharmacy. Mr. Shanehsaz will prepare the letter for review for the Board.

NEXT SCHEDULED MEETING

The next meeting is scheduled for September 20, 2017 at 9:30 Am., 2nd Floor Conference Room.

ADJOURNMENT

There being no other business before the Board, a motion to adjourn the meeting was made by Ms. Robbins and seconded by Ms. Wallner at 1:07 pm. The motion unanimously carried.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mast", written in a cursive style.

Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy